

IFW 1644

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/623,728	
	Filing Date	January 22, 2001	
	First Named Inventor	Zaghouni, H.	
	Art Unit	1644	
	Examiner Name	NOLAN, Patrick	
Total Number of Pages in This Submission	12	Attorney Docket Number	8114-005-WO-CIP.2-US

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input checked="" type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="text"/> Remarks	
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm Name	Catalyst Law Group, APC	
Signature		
Printed name	David M. Kohn	
Date	November 2, 2005	Reg. No. 53,150

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:		
Signature		
Typed or printed name	Sara N. Hare	Date November 2, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



November 2, 2005

CERTIFICATE OF MAILING  
(37 CFR §1.8a)

Under 37 CFR 1.8a I certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date indicated below:

  
Sara N. Hare

November 2, 2005  
Date of Deposit

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Re: US Application No.: 09/623,728**  
**COMPOUNDS, COMPOSITIONS AND METHODS FOR THE**  
**ENDOCYTIC PRESENTATION OF IMMUNOSUPPRESSIVE FACTORS**  
**Filing Date: January 22, 2001**  
**Our Docket No.: 8114-005-WO-CIP.2-US**

Dear Sir:

Enclosed please find the following documents related to the above-identified matter:

1. Transmittal Form (PTO/SB/21) (1 page);
2. Petition Under 37 CFR §1.8(b) For Withdrawal of Improper Abandonment (2 pages);
3. Exhibit A (Amendment and Response to Office Action Dated January 2, 2004) (9 pages); and
4. Self-addressed, stamped postcard

Although there are no fees associated with this submission, please charge any additional fees, or credit any overpayments to Deposit Account Number: 502235.

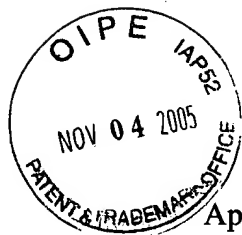
The self-addressed, stamped postcard has been included for your convenience. After confirming receipt of these documents please return the postcard to us at your earliest convenience. Should you have any questions, please do not hesitate to contact me by phone at (858) 450-0099.

Sincerely yours,



David M. Kohn  
Catalyst Law Group, APC  
Reg. No. 53,150

Enclosures



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Zaghouani, H.	Examiner:	NOLAN, Patrick
Serial No.:	09/623,728	Art Unit:	1644
Filed:	January 22, 2001	Attorney Ref. No.:	8114-005-WO-CIP.2-US
Title: COMPOUNDS, COMPOSITIONS AND METHODS FOR THE ENDOCYTIC PRESENTATION OF IMMUNOSUPPRESSIVE FACTORS			

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION UNDER 37 C.F.R. §1.8(b) FOR WITHDRAWAL OF IMPROPER  
ABANDONMENT**

Dear Sir:

1. Applicant hereby respectfully submits the following petition under 37 C.F.R. §1.8(b), allowing Applicant to retain the timely reply date of July 2, 2004 from the previous Office Action response filed in the above identified application.

2. Applicant respectfully acknowledges learning of the Notice of Abandonment sent in application number 09/623,728 on November 1, 2005, which was the date Applicant first had access to the file wrapper of the above mentioned application. Further, Applicant respectfully requests notice of the proffered evidence of the timely filing of the Office Action response which was due July 2, 2004. Such evidence is herewith attached as Exhibit A.

3. Applicant understands, under 37 C.F.R. §1.8(c), the Office may require additional evidence in order to determine whether the correspondence was timely filed. Applicant further directs the Office to the file wrapper in the application, showing the receipt of the Office Action response on July 6, 2004 but still sending out a Notice of Abandonment on July 13, 2004.

Applicant believes this matter to be resolved upon receipt of this Petition and that no fee is due under 37 C.F.R. §1.8(b). Additionally, the patent term will be unaffected if it is found that the Notice of Abandonment was indeed improper. If there are any questions or comments, Applicant's attorney may be reached at the telephone number state below.

Respectfully submitted,

Dated: November 2, 2005

A handwritten signature in dark ink, appearing to read 'DM', is written over a horizontal line.

David M. Kohn  
Registration No. 53,150  
(858) 200-0586

# Exhibit A



## UTILITY/DESIGN PATENT

Date: 7/2/04

Rec'd in the U.S. Patent & Trademark Office on the date stamped hereon via Certificate of mail:

Case # AIIIA. 143C1 S/N: 09/623,728 Filed: 1/22/01

Pat # \_\_\_\_\_ Issued: \_\_\_\_\_

Examiner: P. Nolan Art Unit: 1644 Atty: J. Wurst

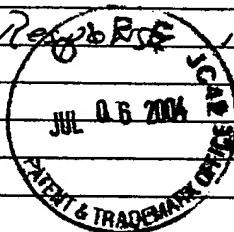
Applicant: Zaghovani, H.

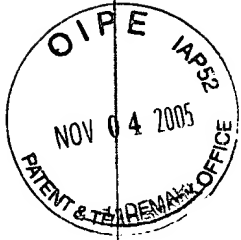
Title: "Compounds, Compositions and Methods  
☐ for the Endocytic Presentation of  
☐ Immunosuppressive Factors"

☒ Amendment and Response in 4 pages

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☐ \_\_\_\_\_  
☐ \_\_\_\_\_  
☐ \_\_\_\_\_  
☐ \_\_\_\_\_

☒ Return Postcard





**ALLIANCE PHARMACEUTICAL CORP.**  
**Attn: Patent Department**  
**6175 Lusk Blvd.**  
**San Diego, CA 92121**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**FREE TRANSMITTAL****for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$) 475

## Complete if Known

Application Number	09/623,728
Filing Date	1/22/2001
First Named Inventor	Zaqhouani, H.
Examiner Name	Nolan, P.
Art Unit	1644
Attorney Docket No.	ALLIA.143C1

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

## Deposit Account:

 Deposit  
Account  
Number  
Deposit  
Account  
Name

01-1008

The Director is authorized to: (check all that apply)

- ☒ Charge fee(s) indicated below ☐ Credit any overpayments  
☒ Charge any additional fee(s) or any underpayment of fee(s)  
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

## 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$)

## 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2)				

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

## 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	475
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1808	180	1808	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 475

## SUBMITTED BY

(Complete (if applicable))

Name (Print/Type)	John E. Wurst	Registration No. (Attorney/Agent)	40,283	Telephone	858-410-5174
Signature	<i>John E. Wurst</i>	Date	July 2, 2004		

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# COPY

PTO/SB/17 (10-03)  
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<h2 style="margin: 0;">FEE TRANSMITTAL</h2> <h3 style="margin: 0;">for FY 2004</h3> <p style="font-size: small; margin: 0;">Effective 10/01/2003. Patent fees are subject to annual revision.</p>		<b>Complete if Known</b>	
<p><input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27</p> <p><b>TOTAL AMOUNT OF PAYMENT</b> (\$ 475)</p>		Application Number <b>09/623,728</b>	
		Filing Date <b>1/22/2001</b>	
		First Named Inventor <b>Zaqhouani, H.</b>	
		Examiner Name <b>Nolan, P.</b>	
		Art Unit <b>1644</b>	
		Attorney Docket No. <b>ALLIA.143C1</b>	

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)																																																																																																																																																																																		
<p><input type="checkbox"/> Check <input type="checkbox"/> Credit card <input type="checkbox"/> Money Order <input type="checkbox"/> Other <input type="checkbox"/> None</p> <p><input checked="" type="checkbox"/> Deposit Account:</p> <p>Deposit Account Number <b>01-1008</b></p> <p>Deposit Account Name _____</p> <p>The Director is authorized to: (check all that apply)</p> <p><input checked="" type="checkbox"/> Charge fee(s) indicated below <input type="checkbox"/> Credit any overpayments</p> <p><input checked="" type="checkbox"/> Charge any additional fee(s) or any underpayment of fee(s)</p> <p><input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.</p>	<h3>3. ADDITIONAL FEES</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1051</td> <td>130</td> <td>2051</td> <td>65</td> <td>Surcharge - late filing fee or oath</td> <td></td> </tr> <tr> <td>1052</td> <td>50</td> <td>2052</td> <td>25</td> <td>Surcharge - late provisional filing fee or cover sheet</td> <td></td> </tr> <tr> <td>1053</td> <td>130</td> <td>1053</td> <td>130</td> <td>Non-English specification</td> <td></td> </tr> <tr> <td>1812</td> <td>2,520</td> <td>1812</td> <td>2,520</td> <td>For filing a request for ex parte reexamination</td> <td></td> </tr> <tr> <td>1804</td> <td>920*</td> <td>1804</td> <td>920*</td> <td>Requesting publication of SIR prior to Examiner action</td> <td></td> </tr> <tr> <td>1805</td> <td>1,840*</td> <td>1805</td> <td>1,840*</td> <td>Requesting publication of SIR after Examiner action</td> <td></td> </tr> <tr> <td>1251</td> <td>110</td> <td>2251</td> <td>55</td> <td>Extension for reply within first month</td> <td></td> </tr> <tr> <td>1252</td> <td>420</td> <td>2252</td> <td>210</td> <td>Extension for reply within second month</td> <td></td> </tr> <tr> <td>1253</td> <td>950</td> <td>2253</td> <td>475</td> <td>Extension for reply within third month</td> <td>475</td> </tr> <tr> <td>1254</td> <td>1,480</td> <td>2254</td> <td>740</td> <td>Extension for reply within fourth month</td> <td></td> </tr> <tr> <td>1255</td> <td>2,010</td> <td>2255</td> <td>1,005</td> <td>Extension for reply within fifth month</td> <td></td> </tr> <tr> <td>1401</td> <td>330</td> <td>2401</td> <td>165</td> <td>Notice of Appeal</td> <td></td> </tr> <tr> <td>1402</td> <td>330</td> <td>2402</td> <td>165</td> <td>Filing a brief in support of an appeal</td> <td></td> </tr> <tr> <td>1403</td> <td>290</td> <td>2403</td> <td>145</td> <td>Request for oral hearing</td> <td></td> </tr> <tr> <td>1451</td> <td>1,510</td> <td>1451</td> <td>1,510</td> <td>Petition to institute a public use proceeding</td> <td></td> </tr> <tr> <td>1452</td> <td>110</td> <td>2452</td> <td>55</td> <td>Petition to revive - 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1502	480	2502	240	Design issue fee																																																																																																																																																																															
1503	640	2503	320	Plant issue fee																																																																																																																																																																															
1460	130	1460	130	Petitions to the Commissioner																																																																																																																																																																															
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)																																																																																																																																																																															
1808	180	1808	180	Submission of Information Disclosure Stmt																																																																																																																																																																															
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1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))																																																																																																																																																																															
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))																																																																																																																																																																															
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<h3>1. BASIC FILING FEE</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1001</td> <td>770</td> <td>2001</td> <td>385</td> <td>Utility filing fee</td> <td></td> </tr> <tr> <td>1002</td> <td>340</td> <td>2002</td> <td>170</td> <td>Design filing fee</td> <td></td> </tr> <tr> <td>1003</td> <td>530</td> <td>2003</td> <td>265</td> <td>Plant filing fee</td> <td></td> </tr> <tr> <td>1004</td> <td>770</td> <td>2004</td> <td>385</td> <td>Reissue filing fee</td> <td></td> </tr> <tr> <td>1005</td> <td>160</td> <td>2005</td> <td>80</td> <td>Provisional filing fee</td> <td></td> </tr> </tbody> </table> <p style="text-align: right;"><b>SUBTOTAL (1)</b> (\$ )</p>	Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1001	770	2001	385	Utility filing fee		1002	340	2002	170	Design filing fee		1003	530	2003	265	Plant filing fee		1004	770	2004	385	Reissue filing fee		1005	160	2005	80	Provisional filing fee		<h3>2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1202</td> <td>18</td> <td>2202</td> <td>9</td> <td>Claims in excess of 20</td> <td></td> </tr> <tr> <td>1201</td> <td>88</td> <td>2201</td> <td>43</td> <td>Independent claims in excess of 3</td> <td></td> </tr> <tr> <td>1203</td> <td>290</td> <td>2203</td> <td>145</td> <td>Multiple dependent claim, if not paid</td> <td></td> </tr> <tr> <td>1204</td> <td>86</td> <td>2204</td> <td>43</td> <td>** Reissue independent claims over original patent</td> <td></td> </tr> <tr> <td>1205</td> <td>18</td> <td>2205</td> <td>9</td> <td>** Reissue claims in excess of 20 and over original patent</td> <td></td> </tr> </tbody> </table> <p style="text-align: right;"><b>SUBTOTAL (2)</b> (\$ )</p>	Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1202	18	2202	9	Claims in excess of 20		1201	88	2201	43	Independent claims in excess of 3		1203	290	2203	145	Multiple dependent claim, if not paid		1204	86	2204	43	** Reissue independent claims over original patent		1205	18	2205	9	** Reissue claims in excess of 20 and over original patent																																																																																																			
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<p><b>Other fee (specify)</b> _____</p> <p>*Reduced by Basic Filing Fee Paid</p> <p><b>SUBTOTAL (3)</b> (\$ 475)</p>																																																																																																																																																																																			

(Complete if applicable)			
SUBMITTED BY		Registration No.	Telephone
Name (Print/Type) <b>John E. Wurst</b>		<b>40,283</b>	<b>858-410-5174</b>
Signature		Date	<b>July 2, 2004</b>

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ALLIA.143C1



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Zaghouani )  
Appl. No. : 09/623,728 )  
Filed : January 22, 2001 )  
For : Compounds, Compositions and )  
Methods for the Endocytic )  
Presentation of Immunosuppressive )  
Factors )  
Examiner : P. Nolan )

Group Art Unit 1644

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: United States Patent and Trademark Office, Commissioner for Patents and Trademarks, P. O. Box 1450, Alexandria, VA 22313-1450 on July 2, 2004:

July 2, 2004  
John E. Wurst  
John E. Wurst

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated January 2, 2004, applicant has the following response:

Apple. No. : 09/623,728  
Filed : January 22, 2001

### REMARKS

Claims 1 - 7 and 21 - 28 are pending in the application. No claims are amended by this response. Applicant hereby applies for a three-month extension of time.

Claims 1 - 7 and 21 - 28 stand rejected over WO 90/09804 ("Zanetti") under 35 USC 102(b). However, applicant respectfully disagrees. Zanetti teaches the use of certain engineered immunoglobulins for the purpose of inducing an immune response to a delivered epitope:

The present invention is based upon the successful production of novel immunoglobulin molecules having introduced into the N-terminus variable region thereof a novel epitope not ordinarily found in the immunoglobulin molecule used as a starting molecule, such epitopes retain specific reactivity. Preferably such reactivity is characterized by the epitope's ability to stimulate an antigenic response. Page 5, lines 8 - 15 of Zanetti (emphasis added).

In fact, Zanetti is concerned mostly with creating a vaccine:

The present invention is further directed to pharmaceutical compositions containing, as essential pharmaceutical principal, a novel immunoglobulin hereof, particularly those in the form of an administratable pharmaceutical vaccine. Zanetti, Page 5, lines 26 - 30.

Examples I and II, the only working Examples in Zanetti, are clearly concerned with generating antibodies to the delivered antigen. For instance, in Example 1, on page 19, it is stated:

To determine whether the recombinant  $\gamma_1$ NANB antibody could be used to induce anti-NANP antibodies, in vivo experiments were performed in rabbits. Two rabbits were immunized with the engineered  $\gamma_1$ NANP antibody, and two controls received the WT Ig. As indicated in Table 1, infra., as early as 30 days after the first immunization, both rabbits immunized with the  $\gamma_1$ NANB antibody, and two controls receive the WT Ig. As indicated in Table I, infra., as early as the 30 days after the first immunization, both rabbits immunized with the  $\gamma_1$ NANB antibody produced anti-NANP antibodies detectable by ELISA and RIA. Zanetti, page 19, lines 8 - 15.

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Pages 19 – 20 go on to discuss an “immunization scheme” with booster injections. Example II is also focused on creating an “antibody vaccine” (see pages 23 – 24).

There are only two brief passages mentioned in Zanetti where it is theorized that the engineered immunoglobulins of Zanetti might be useful in treatments of autoimmune disorders. On page 5, lines 31 – 33, Zanetti states:

The present invention is further directed to methods useful for building tolerance to certain antigens, including those associated with autoimmune diseases, or for down-regulating hypersensitivity to allergens ...

The Abstract of Zanetti states the following:

The epitope-containing immunoglobulins are useful in treating such diseases as autoimmune disorders, as the epitope inserted into the binding domain of the immunoglobulin is capable of inducing or preventing sensitization of the host to that epitope.

It is unclear precisely what strategy Zanetti has in mind for use of his engineered immunoglobulins in “building tolerance to certain antigens” or for “downregulating hypersensitivity to allergens.” These two passages are the only mention of use of immunoglobulins as taught in Zanetti for treatment of autoimmune disorders. There is no mention of how or in what strategy the immunoglobulins of Zanetti would be used to prevent sensitization of the host to an epitope. It is probable that Zanetti is referring to displacement of self-pathogenic peptides and not engagement of autoreactive T cells because displacement of self-pathogenic peptides was a favored strategy at that time. There is no teaching in Zanetti which would lead one to the conclusion that it is the same mechanism of the claimed invention. Thus, it would not be accurate to state that Zanetti is a proper 102(b) reference over the claimed invention which requires “downregulation of autoreactive T cells.” Nothing in Zanetti mentions “T cell receptor agonist for presentation on the surface of said antigen presenting cell ... thereby resulting in downregulation of autoreactive T cells” for the purpose of treating autoimmune disorders. To be a proper 102(b) rejection, every element of the claim must be present must be present in the prior art reference. Richardson vs. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d, 1913, 1920 (CAFC 1989); MPEP 2131. Clearly, not every element of claims 1 – 7 and 21 – 28 are

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Filed : January 22, 2001

taught in Zanetti. Nor would claims 1 - 7 and 21 - 28 be obvious under 35 USC 103(a) over Zanetti in that there is no teaching or suggestion in Zanetti of the claimed invention, that is, the mechanism by which the fusion protein of the claimed invention downregulates autoreactive T cells to treat autoimmune disorders.

Applicant respectfully requests withdrawal of the rejection and allowance of the present application. If there are any questions, applicant's attorney can be reached at the telephone number stated below.

Respectfully submitted,

Dated:

July 2, 2004



John Wurst  
Registration No. 40,283  
(858) 410-5174



# **Notice of References Cited**

Application/Control No.

09/623,728

Applicant(s)/Patent Under  
Reexamination  
ZAGHOUBANI, HABIB

Examiner

Patrick J. Nolan

Art Unit

1644

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 90/09804	09-1990	PCT	Zanetti et al.	
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.